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Clinical research

Intra-aortic balloon counterpulsation in US and non-US centres: results of the Benchmark® Registry

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Aims To examine differences in patient characteristics and outcomes in 19 636 patients enrolled in the USA and 3027 patients enrolled in other countries undergoing intra-aortic balloon pump (IABP) counterpulsation.
Methods and results Indications for IABP use; a larger percentage of US patients were identified as 'early support and stabilization for angiography or angioplasty' (21.1% US vs 11.8% non-US), and 'pre-operative support for high-risk CABG' (15.9% vs 6.6%). A smaller percentage of US patients vs non-US patients were identified as 'weaning from cardiopulmonary bypass' (14.3% vs 28.2%), and 'refractory ventricular failure' (6.2% vs 9.8%). One out of five patients in both groups was listed as 'cardiogenic shock' (18.9% US vs 20.2% non-US). All cause, risk-adjusted, in-hospital mortality (20.1% vs 28.7%; $P<0.001$), and mortality with IABP in place (10.8% vs 18.0%; $P<0.001$) were lower at US vs non-US sites. In both US and non-US institutions, IABP associated complication rates, such as IABP-related mortality (0.05% vs 0.07%), major limb ischaemia (0.9% vs 0.8%), and severe bleeding (0.9% vs 0.8%), were low.
Conclusions IABP counterpulsation is deployed at an earlier clinical stage in US patients. Mortality rates are higher for non-US patients, particularly for patients with non-surgery cardiac interventions, even after adjusting for risk factors. Complication rates were low. Physicians should therefore not be reluctant to use IABP in high-risk patients undergoing cardiac procedures.

Introduction

International registries are important tools for analysing disease management and outcomes among different nations. Exploration of such data may lead to changes in

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Table 1 Patient characteristics and prior history

	Total *n*=22663	US institutions *n*=19636	Non-US institutions *n*=3027	*P* value[a]
Patient age, median (25th, 75th)	67.0 (58,75)	67.0 (58, 75)	67.0 (59, 73)	0.009
Females, n (%)	8363 (36.9)	7369 (37.5)	994 (32.8)	<0.001
Body surface area (m^2), median (25th, 75th)	1.961 (1.801, 2.112)	1.967 (1.806, 2.123)	1.918 (1.779, 2.048)	<0.001
Body mass index, median (25th, 75th)	26.95 (24.30, 30.51)	27.12 (24.39, 30.73)	25.99 (23.80, 28.95)	<0.001
Height, (m), median (25th, 75th)	1.702 (1.626, 1.778)	1.727 (1.626, 1.778)	1.702 (1.626, 1.778)	<0.001
Weight (kg), median (25th, 75th)	79.8 (69, 91)	79.8 (69, 91)	76.2 (68, 85)	<0.001
Previous MI, *n* (%)	6947 (30.7)	5736 (29.2)	1211 (40.0)	<0.001
Diabetes history, *n* (%)	5729 (25.3)	5135 (26.2)	594 (19.6)	<0.001
Previous CABG, *n* (%)	3235 (14.3)	2900 (14.8)	335 (11.1)	<0.001
Peripheral vascular disease, n (%)	2606 (11.5)	2279 (11.6)	327 (10.8)	0.430
Left main coronary artery stenosis, *n* (%)	3754 (16.6)	3400 (17.3)	354 (11.7)	<0.001
Ejection fraction, *n* (%)				<0.001
<35	5346 (23.6)	4751 (24.2)	595 (19.7)	
35–49	3573 (15.8)	3204 (16.3)	369 (12.2)	
>49	3481 (15.4)	2978 (15.2)	503 (16.6)	
Missing	10263 (45.3)	8703 (44.3)	1560 (51.5)	

MI=myocardial infarction; CABG=coronary artery bypass graft.

[a] *P* values for patient age, weight, body surface area, and body mass index were obtained from a one-way comparison of the ranks within the combined sample. *P* values for all other characteristics were obtained using a chi-square test.

national health care policies and disease management strategies.[1] International registries in the United States (US) and Europe have documented regional differences in patient care, and as discrepancies have been identified, have helped to change patient care.[2] Patient treatment can vary substantially from region to region, as can baseline patient characteristics. For example, even within Europe, there is substantial geographic variation in the treatment and evaluation of acute coronary syndromes.[3]

The Benchmark counterpulsation outcomes registry is a prospective registry of all patients who receive an intra-aortic balloon counterpulsation (IABP) at participating institutions. An overview of the outcomes[4] revealed that IABP complication rates are low, although all cause in-hospital mortality remains high, particularly in high-risk patients. The primary aim of the present study is to examine differences in baseline characteristics, patient management, and outcomes between patients in the US and outside the US undergoing IABP from June 1996 through August 2001.

Methods

The Benchmark Counterpulsation Outcomes Registry currently includes 185 US sites and 65 non-US sites that use intra-aortic balloons manufactured by Datascope Corporation, Fairfield NJ, USA. Of the 22 663 patients enrolled in the Benchmark registry, 19 636 (87%) were enrolled in the US, and 3027 (13%) were enrolled in 18 other countries (Appendix A). Any patient at a participating hospital who received an IABP was entered into the database. Patients were registered consecutively to avoid biased selection of cases and were followed to hospital discharge. Concomitant medications were left to the discretion of the treating physician. Information on data collection, handling, and validation has been previously published.[4] Briefly, all data were collected by nurses with oversight provided by site investigators. Three separate audits were used to validate the accuracy of the data.[5] Datascope Corporation provided funding for the database.

Statistics

For quantitative variables, such as age, the Student's *t*-test was applied to the ranks of the observations within the combined sample, a method also known as a rank transformation. For categorical variables, *P* values were determined by using a chi-square test comparing the US distribution versus non-US distribution over the categories. Data on prophylactic use are based on IABP insertion before an intervention (not during or after an intervention). Cardiac interventions were categorized as surgical or non-surgical interventions. If patients had more than one intervention, then only the last intervention was used.

Multiple logistic regression was used to compare the US and non-US in-hospital mortality experience after adjusting for mortality risk factors. Factors were chosen using model-building procedures developed from previous work with the Benchmark Registry. Potential factors were screened and models were generated in a stepwise procedure. First, individual factors were screened using two-way crosstabulations of the factor categories with in-hospital mortality, or by determining whether mortality/non-mortality groups separate the means of continuous factors. Generally, only factors with a statistically significant association ($P<0.05$) were included in the full model. Second, factors chosen in the first step were entered in a full logistic regression model. The effects of collinearity were determined as a reduction of predictive value in the full model of a factor that individually had a strong apparent relationship with in-hospital mortality. Third, non-significant factors ($P>0.05$) were eliminated from the full model in the following order, first interactions, then the individual factors. If an interaction was statistically significant, then the individual factors making up the interaction were automatically retained in the model regardless of their individual significance. Fourth, likelihood

Table 2 IABP Indications, insertion characteristics, and duration indices

	Total *n*=22 663	US institutions *n*=19 636	Non-US institutions *n*=3027	*P* value
Indication for use, n (%)[a]				<0.001
Support and stabilization for angiography and angioplasty	4500 (19.9)	4143 (21.1)	357 (11.8)	
Cardiogenic shock	4314 (19.0)	3702 (18.9)	612 (20.2)	
Wean from cardiopulmonary bypass	3664 (16.2)	2811 (14.3)	853 (28.2)	
Pre-operative high-risk CABG	3319(14.6)	3118 (15.9)	201 (6.6)	
Unstable refractory angina	2618 (11.6)	2296 (11.7)	322 (10.6)	
Refractory ventricular failure	1515 (6.7)	1219 (6.2)	296 (9.8)	
Mechanical complications of AMI	1235 (5.4)	1085 (5.5)	150 (5.0)	
Not indicated; miscellaneous, other (intraoperative pulsatile flow)	960 (4.2)	829 (4.2)	131 (4.3)	
Ischaemia: intractable ventricular arrhythmia	378 (1.7)	290 (1.5)	88 (2.9)	
Cardiac support for high-risk surgery	160 (0.7)	143 (0.7)	17 (0.6)	
SBP before insertion (mmHg) median (25th, 75th)	107.0 (87.0, 129.0)	110.0 (90.0, 131.0)	90.0 (73.0, 110.0)	
IABP insertion location, n (%)[a]				<0.001
Catheterization laboratory	13 990 (61.7)	12 797 (65.2)	1193 (39.4)	
Operating room	5571 (24.6)	4348 (22.1)	1223 (40.4)	
Other, not indicated[a]	3102 (13.7)	2491 (12.7)	611 (20.2)	
Length of hospital stay, days, median (25th, 75th)	11.0 (7, 17)	10.0 (7, 16)	15.0 (10, 23)	<0.001
IABP insertion ⩾5 days after admission, n (%)	3196 (14.1)	2677 (13.6)	519 (17.1)	<0.001
Days from insertion to discharge, median (25th, 75th)	9.0 (7, 15)	9.0 (6,14)	12.0 (9, 20)	<0.001
Days balloon in place, median (25th, 75th)	3.0 (2, 4)	3.0 (2, 4)	3.0 (2, 4)	0.008
Last cardiac surgical intervention prior to IABP, *n* (%)	13 810 (60.9)	11 729 (59.7)	2081 (68.7)	<0.001
CABG, *n* (%)	12 663 (55.9)	10 510 (53.1)	1453 (48.0))	
Non-CABG, *n* (%)	1547 (6.8)	1219 (6.2)	328 (10·8)	
Last PCI prior to IABP, *n* (%)	8853 (39.1)	7907 (40.2)	946 (31.3)	<0.001
Interventional cardiology, *n* (%)	5157 (22.7)	4712 (24.0)	445 (14.7)	
Diagnostic catheterization, *n* (%)	2147 (9.5)	1908 (9.7)	239 (7.8)	
Last intervention not recorded, *n* (%)	1549 (6.8)	1287 (6.6)	262 (8.7)	<0.001

CABG=coronary artery bypass graft; AMI=acute myocardial infarction; SBP=systolic blood pressure; PCI=percutaneous cardiac intervention.

[a]Other=open heart recovery unit, intensive care unit, coronary care unit, and emergency room; percentages do not always total 100% due to missing data.

comparisons to the full model and model-fitting diagnostics were used to judge whether predictive value was lost by removing factors and or interactions. Finally, candidate factors were fitted to a randomly selected subset of records and the resulting logistic regression model coefficients were used to discriminate the mortality/non-mortality subgroups from another disjoint subset of records by computing the predicted logits and measuring the resulting separation of the mortality/non-mortality subgroups.

Table 3 Prophylactic[a] IABC use: incidence by insertion year[b]

	US institutions	Non-US institutions	*P* value
1997	463/2684 (17.3%)	[c]	
1998	971/4720 (20.6%)	48/426 (11.3%)	<0.0005
1999	1387/5344 (26.0%)	102/892 (11.4%)	<0.0005
2000	1517/4850 (31.3%)	224/1138 (19.7%)	<0.0005
2001	576/1842 (31.3%)	96/473 (20.3%)	<0.0005

[a]Prophylactic use is defined as balloon insertion before last intervention.

[b]Comparisons made using chi-square test on unadjusted rates.

[c]In 1997 there were less than 100 international entries.

The risk factors and models differed depending on whether or not patients had a surgical cardiac intervention. Factors that were common to both surgical cardiac and non-surgical cardiac predictor models were age >75 years, body surface area (BSA), initial pre-IABP systolic blood pressure, ejection fraction <30%, peripheral vascular disease, wait for IABP ⩾5 days after hospital admission, insertion year, indication for use listed as 'cardiogenic shock', 'unstable refractory angina', or 'support and stabilization'. Additional factors in the model for patients with surgical cardiac interventions included gender, primary diagnosis=acute myocardial infarction (AMI), previous coronary artery bypass graft (CABG), indication for use 'wean from cardiopulmonary bypass', or 'pre-operative high-risk CABG'. Additional factors in the model for patients with non-surgical cardiac interventions included history of diabetes, previous MI, and ⩾3 vessel disease. The observed US and non-US mortalities were then computed within predicted risk quartiles generated from these logistic regression models, and this provided a

Table 4 Major complication and unadjusted mortality rates for US and non-US institutions[a]

	Total *n*=22 663	US institutions *n*=19 636	Non-US institutions *n*=3027	*P* value
All cause in-hospital mortality, n (%)	4819 (21.3)	3951 (20.1)	868 (28.7)	<0.001
Mortality: balloon in place, n (%)	2669 (11.8)	2125 (10.8)	544 (18.0)	<0.001
Overall major IABP related complications				
IABP-related mortality *n* (%)	12 (0.053)	10 (0.051)	2 (0.066)	0.736
Major limb ischaemia, *n* (%)	194 (0.9)	169 (0.9)	25 (0.8)	0.847
Severe bleeding, *n* (%)[b]	196 (0.9)	173 (0.9)	23 (0.8)	0.790
Balloon failure/leak, *n* (%)	827 (3.6)	704 (3.6)	123 (4.1)	0.341

IABP=intra-aortic balloon pump.

[a] The chi-square test was used on unadjusted rates.
[b] Bleeding at IABP insertion site.

graphical summary of the mortality experience within patient subgroups having similar mortality risk. By subdividing the patients into groups according to the quartiles determined by their estimated risk of death and then comparing the observed mortalities within these risk quartiles, we had the opportunity of observing not just one US/non-US difference, but several differences depending on the patient risk. The formal adjusted comparisons of mortalities were then accomplished by including a US/non-US factor in both the surgery and non-surgery logistic regression models to generate odds ratios from the factor coefficients. For this study, the criterion for statistical significance was P=0.05 and was not adjusted for multiple comparisons.

We analysed risk adjusted mortality rates after excluding all countries that contributed less than 98 cases (Appendix A) and found no change in the results. All analyses were performed using SAS, version 8, using the Windows 98 operating system for an IBM compatible PC.

Endpoints

The primary endpoints included major limb ischaemia, severe bleeding, IABP failure (balloon failure and balloon leak), and all cause in-hospital mortality. All cause in-hospital mortality was defined as mortality occurring from any cause during IABP or after IABP. A secondary endpoint was major IABP-related complications, defined as any major limb ischaemia, severe bleeding, IABP leak, or mortality directly attributed to IABP. Examples of reasons for death attributable to IABP include stroke and multiple emboli to gut with subsequent bowel infarction. Definitions of all endpoints have been previously published.[4]

Results

A series of independent audits used to validate the registry revealed that virtually all IABP procedures at participating sites were included. In addition, accuracy rates were $\geqslant$95% for most categorical variables and $\geqslant$80% for quantitative variables that required a written answer.[5] The high rates of agreement between registry data and patient records support the reliability of the data.

Baseline clinical characteristics for the total population, for US patients, and for non-US patients are shown in Table 1. More US patients were women, had previous CABG surgery, or diabetes, or had an ejection fraction <35%. US patients also tended to be slightly older, taller, heavier, and have a greater body surface area (BSA) and body mass index (BMI). In contrast, more non-US patients had a history of myocardial infarction (MI).

Indications and insertion characteristics

Due to the large number of patients, most of the differences between the US and non-US sites are statistically significant. Thus, we emphasize only the major differences. Overall, the indications and locations of insertion were significantly different (P<0.001). Specifically, a greater percentage of IABP use, at US compared to non-US centres, was to provide early support and stabilization of patients undergoing angiography and angioplasty (21.1% US vs 11.8% non-US), or pre-operative support for high-risk CABG (15.9% vs 6.6%). A smaller percentage of IABP use, at US compared to non-US centres, was for weaning from cardiopulmonary bypass (14.3% vs 28.2%), or refractory ventricular failure (6.2% vs 9.8%) (Table 2). Roughly similar percentages of patients in both groups had IABP for pre-operative support for high-risk general surgery (0.7% vs 0.6%), or for cardiogenic shock (18.9% vs 20.2%). The average length of stay (P<0.001), the number of days from insertion to discharge (P<0.001), and the number of days with IABP in place (P=0.008) were lower in US compared to non-US institutions. Time from hospital admission to IABP insertion was shorter for patients at US centres, with 13.6% of patients receiving IABP $\geqslant$5 days from admission as compared with 17.1% at non-US centres. In the US, 65.2% of insertions were in the catheterization laboratory versus 39.4% in non-US facilities (Table 2). The majority of insertions in non-US sites occurred in the operating room. The insertion was sheathless in 16.6% of US cases and in 41.5% of non-US cases. Lastly, prophylactic IABP use, defined as balloon insertion before last intervention, has increased over time, and is higher in US institutions (31.3% US vs 20.3% non-US in 2001, Table 3).

Complications and mortality rates

Complication and mortality rates, regardless of location, were low, and in specific, major complication rates (IABP-related mortality, balloon failure, balloon leak, major limb ischaemia, and severe bleeding) were extremely low (Table 4). In contrast, overall mortality

Table 5 In-hospital mortality and mortality with balloon in place — incidence by insertion year[a,b]

	Total	US institutions	Non-US institutions	*P* value
In-hospital mortality				
1997	558/2776 (20.1%)	536/2684 (20.0%)	22/92 (23.9%)	0.353
1998	1039/5146 (20.2%)	916/4720 (19.4%)	123/426 (28.9%)	<0.001
1999	1393/6236 (22.3%)	1129/5344 (21.1%)	264/892 (29.6%)	<0.001
2000	1249/5988 (20.9%)	965/4850 (19.9%)	284/1138 (25.0%)	<0.001
2001	545/2315 (23.5%)	371/1842 (20.1%)	174/473 (36.8%)	<0.001
Mortality: ballon in place				
1997	316/2776 (11.4%)	305/2684 (11.4%)	11/92 (12.0%)	0.860
1998	584/5146 (11.3%)	512/4720 (10.8%)	72/426 (16.9%)	<0.001
1999	724/6236 (11.6%)	568/5344 (10.6%)	156/892 (17.5%)	<0.001
2000	687/5988 (11.5%)	505/4850 (10.4%)	182/1138 (16.0%)	<0.001
2001	339/2315 (14.6%)	216/1842 (11.7%)	123/473 (26.0%)	<0.001

[a] Data from 1996 are not included because there were so few international entries in that year.
[b] Chi-square tests applied to unadjusted rates.

rates in this seriously ill population remain high at more than 20%. In the Benchmark registry, all cause unadjusted in-hospital mortality, and mortality with IABP in place, were significantly lower at US institutions (20.1% US vs 28.7% non-US, *P*<0.001), and (10.8% vs 18.0%, *P*<0.001) (Table 4). An investigation of all cause in-hospital mortality and mortality with balloon in place by insertion year reveals that both are consistently higher in non-US institutions (Table 5).

Since it is possible for mortality rates to be higher in non-US sites because patients were simply at higher risk and had more comorbidity, we adjusted for risk factors and analysed the data with multiple logistic regression analysis. After adjusting for risk factors, patients in non-US institutions were still at higher risk for mortality. Patient data were subsequently divided into groups according to predicted mortality based on risk factors. For patients with non-surgical cardiac interventions, mortality in non-US sites was consistently higher in every risk group (Fig. 1). Similarly, mortality was higher in non-US sites for patients with surgical cardiac interventions, although the differences were not consistently significant (Fig. 2). Mortality was significantly higher for non-US patients with non-surgical cardiac interventions whose primary indication was cardiogenic shock (adjusted odds ratio, [95%CI]=1.54, [1.27, 1.87]; *P*<0.001) (Fig. 3).

The logistic regression model that included a non-US versus US term revealed that non-US patients with surgical cardiac interventions had higher all cause in-hospital mortality (adjusted odds ratio, [95% confidence interval (CI)]=1.34, [1.21, 1.49]; *P*<0.001). Non-US patients with non-surgical cardiac interventions also had high all cause in-hospital mortality (adjusted odds ratio, [95% CI]=1.72, [1.51, 1.95]; *P*<0.001).

Mortality with balloon in place was also higher in non-US patients with both surgical cardiac interventions (adjusted odds ratio, [95% CI]=1.48, [1.31, 1.68]; *P*<.0.001) and with non-surgical cardiac interventions (adjusted odds ratio, [95% CI]=1.74, [1.50, 2.02]; *P*<0.001).

Discussion

In US and non-US institutions, IABP is generally associated with a low rate of major complications. However, all cause in-hospital mortality and mortality with balloon in place are higher in non-US sites even after adjusting for risk factors. Potential reasons for this difference in mortality rates include the greater use of IABP in a prophylactic mode at US centres and at an earlier time point in the patients' illness. Whereas the prophylactic use of IABP has also increased at non-US centres, corresponding reductions in mortality may have not been realized as the rate of IABP use for more indications in high-risk patients has also increased. IABP insertion location was more commonly in the catheterization laboratory in US centres and more commonly in the operating room in non-US centres. This difference in insertion location may reflect differences in indications for IABP use — non-US centres use IABPs for surgical cardiac interventions more frequently than US centres. Previous studies support the notion that having a catheterization laboratory can affect treatment approaches and outcomes. For example, the GRACE investigators found substantial differences in treatment approach according to teaching status, presence of catheterization laboratory, and geographic region.[6,7] However, the presence or absence of a catheterization laboratory in the GRACE study was not shown to affect mortality.[7]

Hospital length of stay is also longer in non-US sites. This may be a result of the selection of high-risk patients for IABP. Patients at non-US institutions may also receive their IABP later in the course of their treatment. Combined with lower rates of prophylactic IABP use at non-US sites, this may explain some of the observed differences in mortality rates. It is also possible that US centres may use IABP more commonly in patients who are destined to do well.

Many large international trials have demonstrated substantial variability in outcomes among different countries.[8–10] For example, after adjusting for baseline characteristics, enrolment in the United States was found

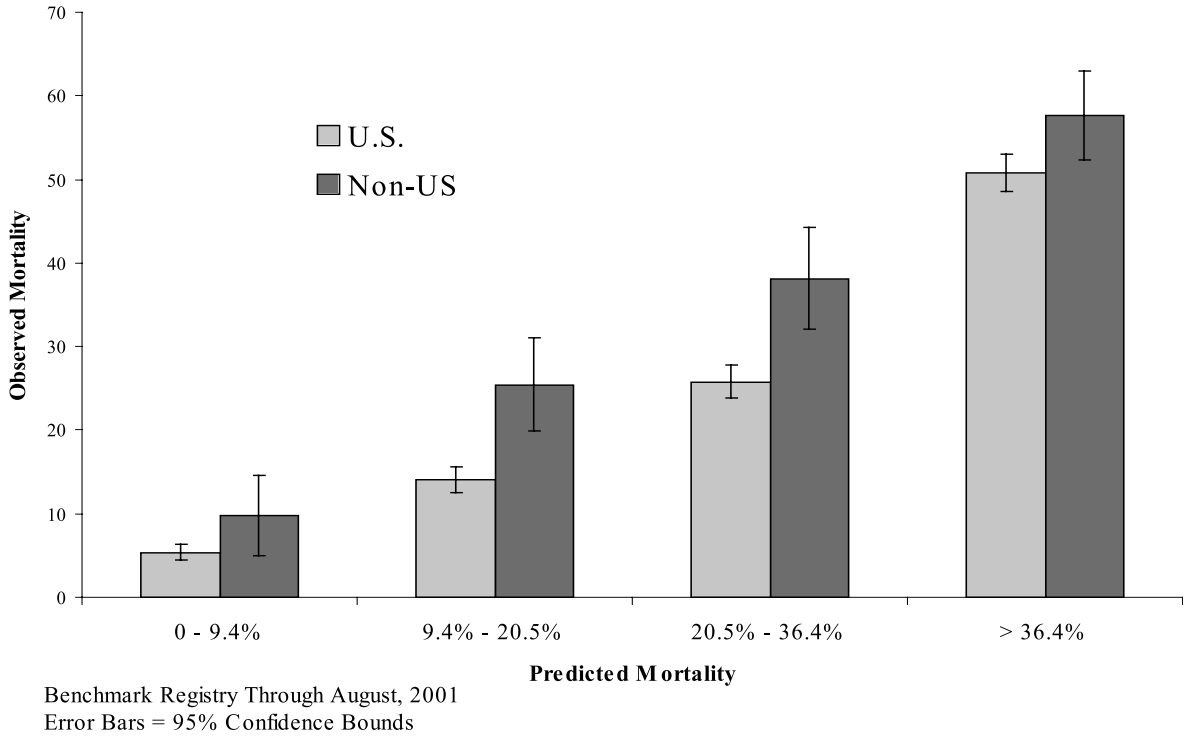

Fig. 1 In-hospital mortality by predicted risk for patients with non-surgical cardiac interventions. Error bars indicate 95% confidence intervals. The predicted mortality categories were based on a logistic regression model combining US and non-US sites. Category boundaries are quartiles of the predicted in-hospital mortalities from the combined cohort of non-surgical cardiac interventions.

to be a marginally significant predictor of better survival in the GUSTO I trial.[8] They also found that more complications were reported in the United States. Even in the United States, there is great variation in the risk-adjusted rates of IABP use between hospitals.[11]

Although IABP use has been shown to be cost-effective and beneficial in high-risk patients,[12–15] controversy persists about appropriate indications for use because of the historically high complication rates.[16,17] However, major complication rates in the Benchmark registry were small, ranging from 0.9% to 2.7%. Physicians should therefore have little reluctance to use IABP in high-risk patients undergoing cardiac procedures. For example, IABP treatment improves the outcomes of patients who have left-main coronary disease,[18] an ejection fraction of <0.25,[19] who are undergoing repeat CABG surgery,[20] or are undergoing cardiac catheterization during myocardial infarction.[14] However, Stone et al, demonstrated no difference in mortality with prophylactic treatment with IABP versus conservative treatment in patients with acute myocardial infarction undergoing percutaneous transluminal coronary angioplasty,[21] although the event rate was extremely low (4.3% vs 3.1%; *n*=437).

Limitations

The limitations of this study are inherent to any large-scale post hoc analysis of prospectively gathered data. Because the registry contains a high number of patients, a difference of just 1% will likely have a significant *P*-value. Although the differences are unlikely to be attributed solely to chance, the clinical importance of the differences must be judged with practical wisdom and clinical experience. In addition, this is not a randomized trial; rather, it is a detailed description of ongoing and evolutionary clinical practice. There may also be site-to-site variations in personnel and resources allocated to the registry, individual practice patterns, and patient populations that are intrinsic to any multinational commercially-sponsored registry.

In the multiple logistic regression analysis, all possible risk factors for mortality were not included in the model. Variables that were not collected as part of the registry could not be included in the analysis.

Conclusions

Indications for IABP use differ between non-US institutions and US institutions. US institutions use IAPB for the early support and stabilization of patients undergoing angiography and angioplasty, pre-operative support for high-risk CABG, and cardiac support for high-risk surgery more frequently than their non-US counterparts. Non-US sites are more likely to use IABP in the treatment of high-risk patients including treatment of cardiogenic shock, weaning from cardiopulmonary bypass, and refractory ventricular failure. Overall, major complication rates are low and physicians should be less reluctant to use IABP in high-risk patients undergoing cardiac procedures. Prophylactic use of IABP has increased over

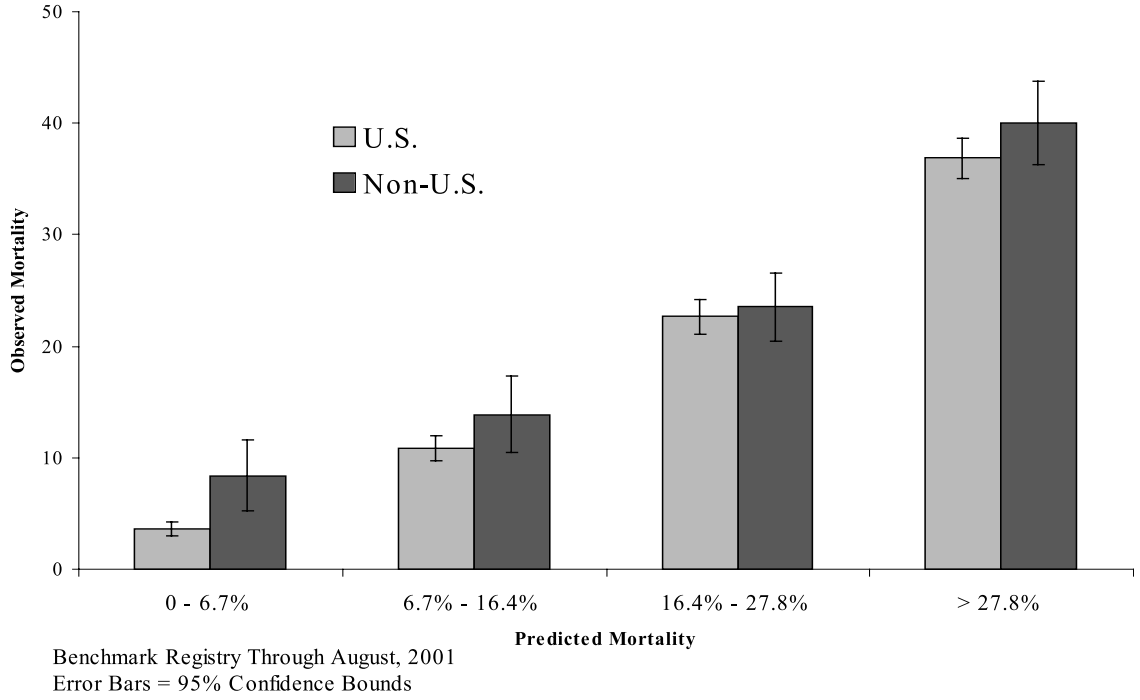

Fig. 2 In-hospital mortality by predicted risk for patients with surgical cardiac interventions. Error bars indicate 95% confidence intervals. The predicted mortality categories were based on a logistic regression model combining US and non-US sites. Category boundaries are quartiles of the predicted in-hospital mortalities from the combined cohort of surgical cardiac interventions.

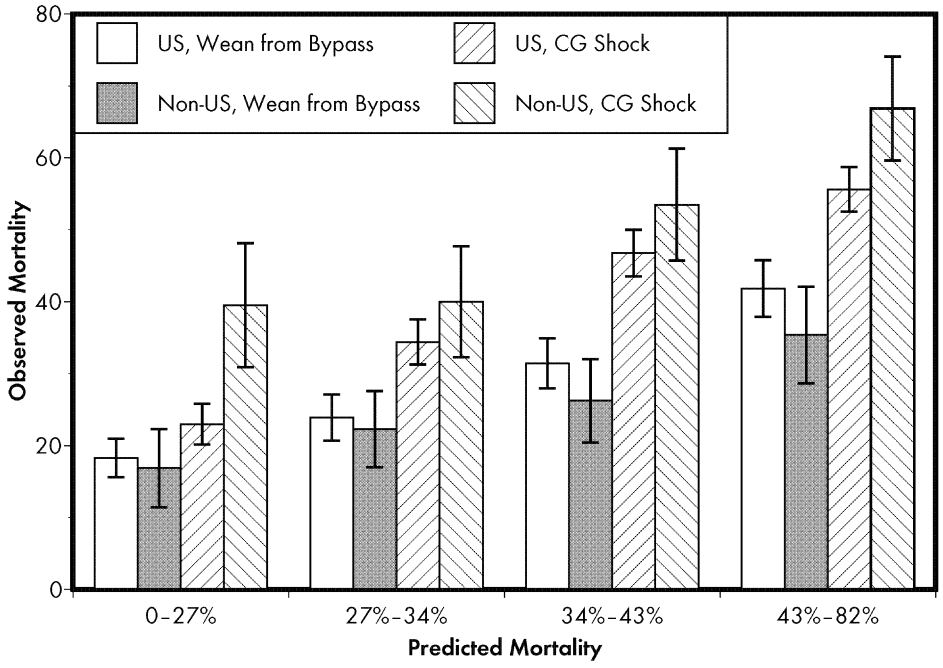

Fig. 3 In-hospital mortality by predicted risk by primary indications. CG=cardiogenic. Category boundaries are quartiles of the predicted in-hospital mortalities from the combined indications.

time, and remains higher in US institutions. All cause in-hospital mortality and mortality with balloon in place are significantly higher for patients undergoing non-surgical interventions at non-US sites even after adjusting for risk factors.

Acknowledgements

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Appendix A

Percentages do not total 100 due to rounding; three missing values for non-US sites

Country	Number of patients
US sites	*n*=19636
Non-US sites	*n*=3024
	n (%)
Canada	755 (25.0)
United Kingdom	710 (23.5)
Germany	521 (17.2)
Belgium	237 (7.8)
New Zealand	155 (5.1)
Ireland	149 (4.9)
Australia	98 (3.2)
France	86 (2.8)
South Africa	84 (2.8)
Denmark	51 (1.7)
Poland	47 (1.6)
Greece	39 (1.3)
Netherlands	34 (1.1)
Switzerland	25 (0.8)
Colombia	16 (0.5)
Scotland	13 (0.4)
Argentina	2 (0.1)
Mexico	2 (0.1)

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